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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,840	12/01/2000	Johnatan Bacon	9463-014-999	4238

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EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	16

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/728,840	Applicant(s) BACON ET AL.	
	Examiner Robert M. Joynes	Art Unit 1615	

-- Th MAILING DATE of this communication app ars on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-19* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on August 26, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal in view of Baichwal. The teachings of Rosenthal and Baichwal are discussed above.

Rosenthal teaches a sustained release composition in which prolamins are present from about 20% to about 45% of the total weight of the composition (Col. 1, lines 33-46). Rosenthal teaches excipients such as starch can be included in the composition (Col. 2, lines 35-39). Starch is a known hydrocolloid material.

Baichwal teaches a sustained release composition comprising an active agent and excipients (Page 2, lines 5-24). The excipient matrix may include one or more heteropolysaccharide, preferably xanthan gum (Page 4, lines27-35), a cross-linking agent (Page 5, line 19 – Page 6, line 3), hydrophobic material such as zein (Page 7, lines 18-32) and an active agent. The hydrophobic material may be present in the composition in amounts from about 1% to about 20% by weight of the final formulation (Page 8, lines 1-10). The active agent may be an antihistamine, analgesic, anti-

inflammatory agent, anti-epileptic agent, anti-emetics agent, vasodilator, anti-tussive agent, anti-asthmatic agent, anti-spasmodic, hormone, diurectic, anti-hypotensive agent, antibiotic and others (Page 12, line 17 – Page 13, line7). The composition may further contain an inert pharmaceutical diluent such as a starch (Page 17, Claim 1). Finally, the amount of hydrophobic material (zein) determines how quickly or slowly the gums hydrate upon exposure to environmental fluid (Col. 6, lines 26-30).

Neither reference teaches the complete concentration ranges recited in the instant claims.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a sustained-release formulation with an excipient matrix comprising a prolamin, one or more gelling agents, one or more additional excipients and an active agent. It is within the skill of the art to vary the ingredient (the prolamin, gelling agents, active agents and additional excipients) to achieve the same expected result. It would be obvious to add a gelling agent to the prolamins of Rosenthal to prepare a sustained release matrix.

One of ordinary skill in the art would have been motivated to do this to produce a composition that releases the active agent over an extended period of time. One would be motivated to add the gelling agent to the prolamins composition of Rosenthal to provide a sustained release composition that forms a gel upon exposure to the environment fluid that causes a better sustained release of the active medicament in the gastrointestinal tract wherein the gel forms, is more rigid and prevent an initial burst of drug when exposed to the environment fluids.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 9-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 5356467). Oshlack teaches a controlled release coating composition comprising zein, a known prolamine (Col. 3, lines 28-61; Col. 5, lines 36-63). The coating composition further comprises pore-forming agents such as hydrophilic polymers, cellulose polymers, polysaccharides, alginates and gums (Col. 8, line 52 – Col. 9, line61). The pore former can be present in the coating from about 0.1% to about 80% (Col. 9,lines 62-66). The core for the coating can be a tablet, sheroid, pellet, microsphere or granule (Col. 7, lines 28-40). A wide variety of active agents can be incorporated into the core to be coated by the coating composition (Col. 10, lines 12-56).

Oshlack does not expressly teach the exact concentration ranges for each component of the coating composition.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a delayed release composition comprising a core containing an active agent that is coated with a composition comprising a prolamine (zein) and a gelling agent (pore-forming agent). With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

One of ordinary skill in the art would have been motivated to do this to provide a controlled release composition wherein the coating of the composition provides a reproducible controlled release of the active agent at a desired rate when exposed to an aqueous environment.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-19 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that the combination of Rosenthal in view of Baichwal is not proper and no motivation exists to combine the references. It is the position of the Examiner that Rosenthal includes ingredients, such as starch, that can be considered gelling agents being that starch is a hydrocolloid material. Baichwal teaches the composition can include gelling agents with prolamines to form controlled release compositions. Therefore, it would be obvious to replace one gelling agent, a starch,

with similar gelling agents as described in Baichwal. One would do so to provide dosage forms that achieve the desired result of a controlled release composition.

Conclusion

Due to the new grounds for rejection, this action is deemed non-final

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
November 17, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600